

REMARKS

Reconsideration and allowance of the subject application are respectfully requested.

Applicants thank the Examiner for courtesies extended to applicants' representative during the telephone interview conducted on October 16, 2007. The amendments and remarks here take into account the discussion and the Examiner's helpful suggestions, especially regarding the objection under §112, first paragraph.

By the above amendments, independent claim 101 is amended to address the Examiner's concerns under §112, first paragraph. Claim 101 is now limited to an SEB DNA fragment encoding a superantigen toxin that has an alteration within positions 40-50 (corresponding to the L45 residue) + at least one alteration within amino acid positions 18-28, 55-65, 62-72, 84-94, 86-96, 89-99, 110-120 and 205-215. The importance of the central leucine of the hydrophobic loop L45 mutation (\pm 5 amino acid residues) is emphasized throughout the disclosure, such as page 17, lines 10-12 ("The mutation of L45 to an arginine reduced overall HLA-DR1 binding greater than 100-fold (Fig. 2b)"). Also see page 19, lines 11-13, 22-25; page 43, lines 1 – 23; Examples 2 and 9. The other amino acid ranges (18-28, 55-65, 62-72, 84-94, 86-96, 89-99, 110-120 and 205-215) are disclosed as viable residues for alteration throughout the specification at page 3, line 30 – page 4, line 16; page 13, lines 7-17; page 14, lines 22 – 34; page 15, line 10 – page 16, line 7; page 17, lines 5-15; page 17, line 29 – page 18, line 2; page 18, lines 17-34; page 19, lines 11 - page 21, line 17; page 22, lines 1 -6; page 43, lines 5-14; page 44, line 29 – page 45, line 29; page 46, line 33 – page 47, line 8; and Examples 3 and 4.

Claims 102 and 115 are canceled without prejudice or disclaimer. Claim 102 is believed to be supported by the specification, particularly in connection with the disclosure of the altered superantigen toxin B899445 discussed throughout our specification. However, in the interest of advancing prosecution we have canceled this claim. Claim 115 is canceled because it is now redundant in light of the amendments to independent claim 101.

No new matter is introduced by the amendments to claim 101, which is now more limited in scope by requiring the L45 mutation (\pm 5 amino acid residues) to be present in the mutant SEB superantigen toxin—before, it was one of many optional alterations. For the same reason, and further because exactly the same amino acid mutations are reflected in the claims, no additional search needed. This is expected to remove the rejection of the claims under §112, first paragraph. As discussed below, the rejection under §102(a) over Bavari is believed to be overcome by submission of a Katz Declaration. Thus, these claim amendments and the appended Katz Declaration reduce the number of issues on appeal. Entry and consideration are therefore requested.

Claims 101-115 are rejected on the ground of obviousness-type double patenting over claims 1-30 of parent application U.S. Patent 6,713,284. The claims are not identical, but the Examiner is contending that they are not patentably distinct due to significant overlap in claim scope. As discussed with the Examiner during the telephone interview, applicants will submit an appropriate terminal disclaimer to address this issue. The applicants are locating the relevant assignment document to confirm its recordal; when that is determined, we will submit the terminal disclaimer as soon as possible.

Claims 101-115 are rejected under 35 U.S.C. §112, first paragraph, as containing new matter not included in the original written description, and claim 101 in particular. The Examiner is requesting us to point out where in the specification there is support for claim 101, since the “concept of combining mutations in this way to result in the recited properties is not seen in the specification”.

Following the guidance of the Examiner during the telephone interview, and to facilitate allowance of this application, independent claim 101 is now amended to recite an SEB DNA fragment that has an alteration within positions 40-50 (corresponding to the L45 residue of the hydrophobic loop) + at least one alteration within amino acid positions 18-28, 55-65, 62-72, 84-94, 86-96, 89-99, 110-120 and 205-215. The importance of the central leucine of the hydrophobic loop L45 mutation (\pm 5 amino acid residues) is emphasized throughout the disclosure, and now all of the claims require its presence in the SEB mutant, along with at least one more amino acid alteration selected from the specified list. The specification describes the preferred L45 hydrophobic loop mutation

and the desirability of combining it with at least one other mutation, such as alterations within the polar binding pocket (positions 62-72, 84-84 and 110-120), non-conserved receptor binding surface (positions 89-99), and conserved residues of integral molecular surfaces which contact T-cell antigen receptors (positions 18-28, 55-65, 86-96, and 205-215). Support within the specification for this amendment is provided above. This revision of claim 101 is believed to address the Examiner's concerns, and reconsideration of this rejection is requested.

Claims 101, 103, 104, 106 and 115 are rejected as anticipated by Bavari et al. ("Engineered Bacterial Superantigen Vaccines", Vaccines 96, Cold Spring Harbor Laboratory Press, pages 135-141, 1996). This Bavari reference was published within one year of the filing date of this application and is the inventors' own work. To that end, we submit here a copy of a Katz Declaration that was filed March 22, 1999 in parent patent U.S. 6,713,284. The Declaration is signed by all of the inventors, and verifies that the only non-inventor author of Bavari, Beverly Dyas, did not make an inventive contribution to the claimed invention. This is believed sufficient to remove Bavari et al. as a citable reference. Withdrawal of this rejection is believed to be in order.

In summary, all of the Examiner's outstanding rejections and objections have been addressed, and the application is believed to be in allowable form. Notice to that effect is earnestly solicited. No amendment made was related to the statutory requirements of patentability unless expressly stated herein, and no amendment made was for the purpose of narrowing the scope of any claim unless we argued above that such amendment was made to distinguish over a particular reference or combination of references.

App. of Ulrich et al.
Ser. no. 10/767,687
Amdt. Responsive to Office Action dated July 31, 2007

If the Examiner has any questions or would like to make suggestions as to claim language, she is encouraged to contact Marlana K. Titus at (301) 977-7227.

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